REMARKS

Claims 1-10 and 12-13 are pending in the present application after entry of this Amendment. New Claims 12 and 13 have been added. Support for these claims is found on page 10 of the specification at lines 6-11 and in Example 1. Applicant requests entry of the Amendment consideration of the remarks below.

Specification

Applicant has amended the paragraph on page 8, beginning at line 9, to remove the embedded hyperlink as requested by the Examiner.

35 U.S.C. §112, second paragraph

The Examiner rejected claims 9-10 under 35 U.S.C. §112, second paragraph as being indefinite. Applicant has amended claims 9-10 to address this rejection.

Claim 9 has been amended to recite wherein said "vector" is mammalian expression vector. The term "vector" finds antecedent basis in claim 1.

Applicant has amended claim 10 for clarity. Claim 10 now recites the method of Claim 1 wherein after a change in activity is determined, said method further comprises the additional steps of dividing said plurality of candidate agents into subsets each containing an individual candidate agent, and introducing said individual candidate agent into an other cell, wherein said other cell comprises a transcription factor of interest and a vector comprising a binding site for a transcription factor of interest operatively linked to a reporter gene, and determining the activity of said transcription factor, wherein a change in activity between the presence and absence of said candidate agent indicates a candidate agent which modulates transcription factor activity. Thus Claim 10 requires that the dividing of the plurality of candidate agents occurs after the steps of claim 1 are performed.

35 U.S.C. §102(e)

Glimcher

Claims 1-4 and 6-10 are rejected under 35 U.S.C. §102(e) as being anticipated by Glimcher et al. (US Patent No. 5,958,671). To anticipate a claim, the reference must teach every element of the claim. M.P.E.P §2131. Applicant respectfully submits that Glimcher does not teach every element of claims 1-4 and 6-10.

Claim 1, the only independent claim, recites a method for screening for an agent which modulates transcription factor activity, comprising providing a cell comprising a transcription factor of interest and a vector comprising a binding site for said transcription factor of interest operatively linked to a reporter gene, introducing **a plurality of candidate agents** to said cell and determining the activity of said transcription factor, wherein a change in activity between the presence and absence of said candidate agents indicates the presence of an agent which modulates transcription factor activity. Thus, claim 1 is directed toward assaying a plurality of candidate agents.

Glimcher is directed to the study of methods of modulating production of Th2-associated cytokines by modulating the activity of a transcription factor, c-Maf. One of the aspects disclosed by Glimcher involves screening assays for identifying a compound that modulates the activity of a transcription factor that regulates expression of a Th2-associated cytokine gene. However, the assays of Glimcher are limited to the screening of individual compounds. Subsection V of Glimcher is directed to screening assays which comprise contacting **"a test compound"** with an indicator cell comprising a recombinant expression vector encoding a transcription factor that regulates expression of a Th2-associated cytokine gene and a vector comprising regulatory sequences of the Th2-associated cytokine gene operatively linked to a reporter gene, and identifying **"a compound"** that modulates the activity of the transcription factor that regulate expression of a Th-2 associated cytokine gene. Thus, Glimcher does not teach the introduction of a plurality of candidate agents into the indicator cell. Because Glimcher does not teach every element of claim 1, it cannot anticipate claim 1, or claims 2-4 and 6-10 dependent thereon. Applicant respectfully requests withdrawal of the rejection.

Claim 10 is directed toward the method of Claim 1 wherein after a change in activity is determined, said method further comprises the additional steps of dividing said plurality of candidate agents into subsets each containing an individual candidate agent, and introducing said individual candidate agent into an other cell, wherein said other cell comprises a transcription factor of interest and a vector comprising a binding site for a transcription factor of interest operatively linked to a reporter gene, and determining the activity of said transcription factor, wherein a change in activity between the presence and absence of said candidate agent indicates a candidate agent which modulates transcription factor activity. Glimcher does not teach the additional steps of dividing a plurality of candidate agents determined to change the activity of a transcription factor into subsets each containing an individual candidate agent and introducing the individual candidate agent into an other cell for further analysis.

Additionally, the Examiner asserts that Glimcher anticipates claim 2 because Glimcher teaches the agent that modulates transcription factor activity can be a cDNA clone from an expression library. The Examiner points to column 8, line 62, to column 9, line 31 and column 14, lines 25-44, for support for the assertion. Applicant respectfully submits that Glimcher does not teach the use of cDNA clones from expression libraries as potential agents. Column 8, line 62, to column 9, line 31 discloses the cloning and expression of the transcription factor (specifically mentioned is the maf transcription factor), not of an agent that modulates the activity of the transcription factor. Column 14 discloses the cloning of antisense nucleic acids but makes no mention of the creation of expression libraries.

Furthermore, the Examiner asserts that Glimcher anticipates claim 3 because Glimcher teaches introducing into the indicator cell a control plasmid comprising a constitutively expressed gene to monitor transfection efficiency. The Examiner cites to column 11 for support for the assertion. Applicant respectfully submits that Glimcher does not teach the use a control plasmid comprising a constitutively expressed gene to monitor transfection efficiency . Rather, Glimcher, at column 11, discloses the use of use of a selectable marker to identify and select stably transfected cells but makes no mention of the use of a second plasmid to monitor transfection efficiency. As such, Glimcher does not teach the use of a control plasmid comprising a constitutively expressed gene to monitor transfection efficiency and cannot anticipate claim 3.

Applicant respectfully requests withdrawal of the rejection.

Kushner

Claims 1 and 3-10 are rejected under 35 U.S.C. §102(e) as being anticipated by Kushner et al. (US Pub. No. US2002/0098477). To anticipate a claim, the reference must teach every element of the claim. M.P.E.P §2131. Applicant respectfully submits that Kushner does not teach every element of claims 1 and 3-10.

Claim 1, the only independent claim, recites a method for screening for an agent which modulates transcription factor activity, comprising providing a cell comprising a transcription factor of interest and a vector comprising a binding site for said transcription factor of interest operatively linked to a reporter gene, introducing **a plurality of candidate agents** to said cell and determining the activity of said transcription factor, wherein a change in activity between the presence and absence of said candidate agents indicates the presence of an agent which modulates transcription factor activity.

Kushner is directed to the study of methods for screening nuclear transcription factor ligands for the ability to modulate estrogen activation at an AP-1 site. As with Glimcher, Kushner discloses screening assays comprising contacting "**an agent**" with an indicator cell (page 2, paragraph 0017). The effect of "**the agent**" on transcription factor ligand modulation is then determined (page 5, paragraph 0045). Thus, Kushner does not teach the introduction of a plurality of candidate agents into the indicator cell. As such, Kushner does not anticipate claim 1 or claims3-10 dependent thereon.

Additionally, as discussed above, Claim 10 is directed toward the method of Claim 1 wherein after a change in activity is determined, said method further comprises the additional steps of dividing said plurality of candidate agents into subsets each containing an individual candidate agent, and introducing said individual candidate agent into an other cell, wherein said other cell comprises a transcription factor of interest and a vector comprising a binding site for a transcription factor of interest operatively linked to a reporter gene, and determining the activity of said transcription factor, wherein a change in activity between the presence and absence of said candidate agent indicates a candidate agent which modulates transcription factor activity. Kushner does not teach the additional steps of dividing a plurality of candidate agents determined to change the

activity of a transcription factor into subsets each containing an individual candidate agent and introducing the individual candidate agent into an other cell for further analysis.

Applicant respectfully requests withdrawal of the rejection.

35 U.S.C. §103

Claim 5 is rejected under 35 U.S.C. §103 as being obvious over Glimcher et al. (US Patent No. 5,958,671) in view of Kushner et al. (US Pub. No. US2002/0098477). There are three requirements to establish a *prima facie* case of obviousness: 1) there must be some suggestion or motivation, either in the references or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine the reference teachings; 2) there must be a reasonable expectation of success; and 3) the prior art reference must teach or suggest all the claim limitations. M.P.E.P §2143.

Claim 5 is dependent on claim 1. Thus claim 5 recites a method for screening for an agent which modulates transcription factor activity, comprising providing a cell comprising a transcription factor of interest and a vector comprising a binding site for said transcription factor of interest operatively linked to a reporter gene, introducing **a plurality of candidate agents** to said cell and determining the activity of said transcription factor, wherein a change in activity between the presence and absence of said candidate agents indicates the presence of an agent which modulates transcription factor activity wherein the reporter gene encodes a fluorescent protein.

As set forth in the section above discussing anticipation, neither Glimcher nor Kushner teach an assay which comprises the introduction of **a plurality** of candidate agents. Thus, neither Glimcher nor Kushner teach all of the elements of independent claim 1. Neither do either reference suggest that the assays disclosed therein may find applicability for the testing of a plurality of agents. Because the combination of Glimcher and Kushner do not teach or suggest every element of claim 5, claim 5 cannot be held obvious over these references. Applicant requests withdrawal of this rejection.

Applicants respectfully submit that the claims are in condition for allowance and an early notification of such is solicited.

Please direct any calls in connection with this application to the undersigned at (415) 781-1989.

Respectfully submitted,

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